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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,969	02/22/2002	Cheng Cheng	4-31704A/GTI	4496

1095 7590 09/10/2003

THOMAS HOXIE  
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 430/2  
EAST HANOVER, NJ 07936-1080

EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1636

12

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/081,969

Applicant(s)

CHENG ET AL.

Examiner

Maria B Marvich, PhD

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-14, 16-45, 47-51, 58-59, 61-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, 16-38, 40, 41, 48-51, 58 and 59 is/are allowed.
- 6) ☒ Claim(s) 7-9, 16, 39, 42, 43, 61, 62 and 64 is/are rejected.
- 7) ☒ Claim(s) 10, 11, 13, 14, 44, 45, 47, 63, 65 and 66 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This office action is in response to an amendment filed 7/1/03, Paper No. 11. Claims 4, 7, 10-11, 13, 18-25, 27, 29-32, 34-37, 44-45 and 47 have been amended. Claims 12, 15, 46, 52-57 and 60 have been canceled. Claims 61-66 have been added. Claims 1-11, 13-14, 16-45, 47-51, 58-59 and 61-66 are pending. An IDS filed 5/8/03, Paper No. 10 has been received and the document considered. There is a new rejection herein, and therefore this rejection is Non-Final.

#### ***Response to Amendment***

Rejection of claims 18-37, 52-57 and 60 under 35 U.S.C. 112, first paragraph, due to lack of enablement is withdrawn in light of amendment to claims. Specifically, claims 18-37 have been amended to remove the limitation that the genes encoded by the adenoviral vector are therapeutic genes and Claims 52-57 and 60 have been cancelled.

Rejection of claims 4, 10, 13, 22, 25, 27, 30-32, 34, 44 and 47 under 35 U.S.C. 112, second paragraph, is withdrawn in light of amendment to claims. Specifically, the cited claims have been amended.

Rejection of claims 10, 12-13, 15, 23-24, 26, 30, 31, 33, 35, 37, 44 and 46-47 under 35 U.S.C. 112, first paragraph, for lack of written description, is withdrawn in light of amendment to claims. Specifically, applicants have amended claims 10, 13, 15, 24, 26, 30, 33, 33, 35, 37, 44 and 47. Claims 12, 15 and 46 have been cancelled.

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***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). The citizenship of Mario Gorziglia as of Venezuela has been changed to American M6 US. It should be noted that the ADS also lists Mr. Gorziglia's citizenship as Venezuela.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 61 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Braun et al.

US 6,258,791 B1, see entire document. **This is a new rejection necessitated by amendment.**

Braun et al. teach a luciferase reporter gene encoded by an adenoviral vector and under control of Ad2MLP promoter and SV40 polyadenylation signal which are downstream of the left ITR (see e.g. column 8, line 66 through column 9, line 22).

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Claims 61 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Johns et al. US 6,214,620, see entire document. **This is a new rejection necessitated by amendment.**

Johns et al. teach a recombinant viral vector as shown (see e.g. Figure 1A) comprising an adenoviral backbone with an SV40 polyadenylation signal downstream of the left ITR.

Claims 61 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Patel et al. US 6,420,345 B1, see entire document. **This is a new rejection necessitated by amendment.**

Patel et al. teach cyclin dependent kinase inhibitor (CDKi) protein encoded by an adenoviral vector and under control of the CMV promoter and SV40 polyadenylation signal which are downstream of the left ITR (see e.g. Figure 7 and column 32, line 1-34).

Claims 61 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Lieber et al. WO 01/83796 A2, see entire document. **This is a new rejection necessitated by amendment.**

Lieber et al. teach generation of an adenoviral vector expressing B-gal under control of the RSV promoter and SV40 polyadenylation signal which are downstream of the left ITR (see e.g. Figure 7A).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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13 mm  
Claim 7-9, 16, 39, 42-43 and 62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is unclear for reciting “corresponding base pairs of other Adenovirus serotypes”. It is unclear what the metes and bounds of the claim are. It would be remedial to recite “or the corresponding functions in other adenoviral serotypes”. **This rejection is maintained for reasons of record in the office action filed 3/26/03, Paper No. 9.**

Claim 8 recites the limitation "the E3 region" in claim 1. There is insufficient antecedent basis for this limitation in the claim. It would be remedial to recite “wherein the adenoviral backbone comprises the E3 region comprising a mutation or deletion”. **This is a new rejection.**

Claim 9 recites the limitation "a tissue-specific promoter operably linked to E4" in claim 5. There is insufficient antecedent basis for this limitation in the claim. It would be remedial to recite “wherein the adenoviral backbone comprises the E4 region which is operably linked to a tissue specific promoter”. **This is a new rejection.**

Claim 16 recites the limitation "the E1b region" in claim 1. There is insufficient antecedent basis for this limitation in the claim. It would be remedial to recite “wherein the adenoviral backbone comprises the E1b region comprising a mutation or deletion”. **This is a new rejection.**

Claim 17 recites the limitation "the active 19kD protein" in claim 16. There is insufficient antecedent basis for this limitation in the claim. **This is a new rejection.**

Claim 39 recites the limitation "tumor selectivity" in 38. There is insufficient antecedent basis for this limitation in the claim. **This is a new rejection.**

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Claim 42 recites the limitation "the E1b region" in claim 40. There is insufficient antecedent basis for this limitation in the claim. It would be remedial to recite "wherein the adenoviral backbone comprises the E1b region comprising a mutation or deletion". **This is a new rejection.**

Claim 43 recites the limitation "a tissue-specific promoter operably linked to E4" in claim 40. There is insufficient antecedent basis for this limitation in the claim. It would be remedial to recite "wherein the adenoviral backbone comprises the E4 region which is operably linked to a tissue specific promoter". **This is a new rejection.**

Claim 62 recites the limitation "the coding region" in claim 61. There is insufficient antecedent basis for this limitation in the claim. **This is a new rejection necessitated by amendment.**

### ***Response to Arguments***

Applicants traverse the claim rejections under 35 U.S.C. 112, second paragraph in the amendment filed 7/1/03, Paper No. 11. Applicant states that "corresponding base pairs of other Adenovirus serotypes" encompasses functions of this region in other serotypes. Specifically, a corresponding deletion in another serotype would delete that serotype's native packaging signal.

Applicant's arguments filed 7/1/03 have been fully considered but they are not persuasive. By reciting "or other corresponding base pairs of other Adenoviral serotypes", it is not clear that functionally related regions are intended by the recited language. As the base pairs



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are referred to as corresponding (equivalent or parallel), as written the base sequences themselves are "corresponding" and not the functionally equivalent region.

***Conclusion***

Claims 7-9, 16-17, 39, 42-43, 61-62 and 64 are rejected.

Claims 1-6, 18-38, 40-41, 48-51 and 58-59 are allowable.


Claims 10-11, 13-14, 44-45, 47, 63, and 65-66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

  
REMY YUCEL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600